

Remarks

The Amendments to the Claims

Claims 2, 3, 6, 8, and 12 have been amended to delete the recitation “the open reading frame contained within” the nucleotide sequence shown in SEQ ID NO:1. Originally filed claims 2, 3, 6, 8, and 12, which did not contain the recitation “the open reading frame contained within,” support this amendment. Withdrawn claims 13, 15, 27, 33, and 37 have similarly been amended and are similarly supported by originally filed claims 13, 15, 27, 33, and 37. Thus the amendment adds no new matter to the application. The amendment will not require further search or consideration because the Patent Office considered the claims, as amended in this paper (*i.e.*, as originally filed), in the Office Action dated February 25, 2004. The amendment was not earlier made because claims 2, 3, 6, 8, and 12 were first rejected in the final Office Action over the now-deleted recitation. We also believe the amendment places the claims in condition for allowance.

Applicants respectfully request entry of the amendment.

Supplemental Declaration of Mr. Zhelnin and Dr. Bloomquist

Applicants respectfully request consideration of the supplemental declaration of the inventors, Mr. Zhelnin and Dr. Bloomquist, under 37 C.F.R. § 131. The supplemental declaration was not submitted earlier because Applicants believed that Mr. Zhelnin’s and Dr. Bloomquist’s originally filed declaration under 37 U.S.C. § 131 sufficiently established conception and reduction to practice of the claimed invention prior to Valenzuela’s publication date, discussed below.

The Rejection of Claims 2, 3, 6, 8, and 12 Under 35 U.S.C. § 112, First and Second Paragraphs

Claims 2, 3, 6, 8, and 12 are rejected under 35 U.S.C. § 112 first paragraph as lacking adequate description in the specification and under 35 U.S.C. § 112 second paragraph as indefinite.

The Office Action asserts that claims 2, 3, 6, 8, and 12 are not adequately described in the specification and that the recitation “the open reading frame contained within” the nucleotide sequence of SEQ ID NO: 1 is unclear. To advance prosecution, applicants have deleted this recitation from the rejected claims.

Applicants respectfully request withdrawal of these rejections.

The Rejection of Claims 1-8 and 12 Under 35 U.S.C. § 102(a)

Claims 1-8 and 12 stand rejected under 35 U.S.C. § 102(a) as anticipated by Valenzuela *et al.*, WO 00/11015 (“Valenzuela”). Applicants respectfully traverse the rejection.

Claims 1, 5, 7, and 12 are the independent claims of the rejected claim set. Claim 1 is directed to an isolated polynucleotide encoding a polypeptide that comprises the amino acid sequence shown in SEQ ID NO: 2. Claim 5 is directed to an expression vector comprising a polynucleotide that encodes a polypeptide comprising the amino acid sequence shown in SEQ ID NO: 2. Claim 7 is directed to a host cell comprising the expression vector. Claim 12 is directed to a method of producing a polypeptide comprising the amino acid sequence shown in SEQ ID NO: 2. The method employs a host cell comprising an expression vector that comprises the nucleotide sequence shown in SEQ ID NO: 1. Valenzuela is cited as teaching amino acid and nucleotide sequences identical to SEQ ID NOS: 2 and 1, respectively. Valenzuela, however, does not anticipate the invention of claims 1-8 and 12.

Section 102(a) of 35 U.S.C. states that:

A person shall be entitled to a patent unless – (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

The applicants for patent, Mr. Zhelnin and Dr. Bloomquist, conceived of and reduced the invention to practice prior to the publication date of Valenzuela. In response to the Office Action dated February 25, 2004 applicants submitted a declaration under 37 C.F.R. § 131 as evidence that applicants invented the subject matter of the rejected claims prior to Valenzuela's publication date.

The final Office Action asserts that the declaration was not adequate to overcome the rejection because it did not clearly explain that applicants arrived at the full sequence of the SEQ ID NO: 1 prior to the Valenzuela publication and because its attached exhibits were of poor quality. Final Office Action at page 3, lines 8-15. Applicants submit a supplemental declaration of Mr. Zhelnin and Dr. Bloomquist under 37 C.F.R. §1.131 to directly address the each of these issues. The supplemental declaration explicitly describes each step of the conception and reduction to practice of SEQ ID NO: 1 and SEQ ID NO: 2 and compares the nucleotide sequences obtained at each of these steps to the sequences of SEQ ID NO: 1 and SEQ ID NO:2. Applicants also submit additional exhibits relative to those filed with the initial declaration and higher quality copies of the exhibits than those filed with the initial declaration to assist the Patent Office in understanding their conception and reduction to practice of the invention.

The supplemental declaration establishes that the inventors received reports from a Gene Agent program identifying sequences having homology to orexin-2 and NPY1 receptors. See ¶

3. The inventors used the nucleotide sequence of one of the sequences identified by the Gene Agent program, AC005961.1, to begin their efforts to clone a novel GPCR. See ¶ 7.

The inventors designed primers using the AC005961.1 sequence to amplify a portion of the GPCR from human genomic DNA. See ¶ 9. The amplification reaction produced a 161 base pair amplification product. See ¶ 10 and Exhibit 4. Nucleotides 11-153 of the 161 base pair amplification product shared identity with nucleotides 167-309 of SEQ ID NO: 1. See ¶ 10 and Exhibit 5.

The inventors obtained 5' sequence to the 161 base pair amplification product by 5'-RACE. See ¶ 12. 5'-RACE produced two clones, a 210 base pair clone and a 347 base pair clone, that assembled with the 161 base pair amplification product described in ¶ 10. The assembled sequence, named "5GA1," contained 347 base pairs. See ¶ 16 and Exhibit 9. The amino acid sequence encoded by 5GA1 shared identity with amino acid residues 1-103 of SEQ ID NO: 2. See ¶ 18 and Exhibit 10. The nucleotide sequence of 5GA1 shared identity with nucleotides 1-309 of SEQ ID NO: 1. See ¶ 19 and Exhibit 11. Therefore, 5'-RACE extended the sequence which would become SEQ ID NO: 1 from 167-309 (the sequence of the 161 base pair amplification product described in ¶ 10) to 1-309.

The inventors obtained 3' sequence to the 161 base pair amplification product described in ¶ 10 by 3'-RACE. See ¶ 21. The products of 3'-RACE, a 650 base pair and a 730 base pair amplicon, had overlapping nucleotide sequences. The overlapping sequences were developed into a single 3'-RACE clone, "3'-RACE #2," which was 913 base pairs in length. See ¶ 25. The nucleotide sequence of the 3'-RACE #2 clone was identical to nucleotides 203-1017 of SEQ ID NO: 1. See ¶ 25 and Exhibit 14A. The 3'-RACE #2 clone encoded an amino acid sequence identical to amino acid residues 78-339 of SEQ ID NO: 2. See ¶ 25 and Exhibit 14B.

The inventors assembled the nucleotide sequence of 5GA1 described in ¶ 16 and the 3'-RACE #2 described in ¶ 25 into a 1036 nucleotide virtual clone. The virtual clone was identical to nucleotides 1-1017 of SEQ ID NO: 1. See ¶ 26 and Exhibit 15. The virtual clone encoded 345 amino acids that were identical to amino acid residues 1-339 of SEQ ID NO: 2. See ¶ 27 and Exhibit 15. Thus, assembly of 5GA1 and 3'-RACE #2 extended the sequence which would become SEQ ID NO: 1 from 1-309 (the sequence of 5GA1 described in ¶ 16) to 1-1017.

The inventors then performed BLAST analysis to identify the 3' end of the GPCR. BLAST analysis identified a 279 nucleotide region that putatively contained the 3' end of the GPCR. See ¶ 31. The 279 nucleotide region was identical to nucleotides 1018-1296 of SEQ ID NO: 1. See ¶ 32 and Exhibit 20.

The inventors PCR amplified clones containing the complete 1296-bp ORF from both human heart and brain cDNA. See ¶ 34. The inventors confirmed the coding sequence of the GPCR full-length clone by sequence analysis of a full-length amplicon generated by amplification of human brain cDNA clones. See ¶ 35. The confirmation sequence was identical to SEQ ID NO: 1. See ¶ 36 and Exhibit 22. The amino acid sequence encoded by the confirmation sequence was identical to SEQ ID NO: 2. See ¶ 37 and Exhibit 23.

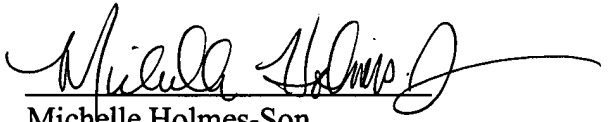
The inventors' declaration, summarized above, establishes that before the March 2, 2000 publication date of Valenzuela, Applicants reduced to practice a polynucleotide comprising the open reading frame contained within the nucleotide sequence of SEQ ID NO:1; this polynucleotide encodes the amino acid sequence of SEQ ID NO:2. Thus, Valenzuela does not anticipate claims 1-8 and 12.

Applicants respectfully requests withdrawal of this rejection.

Respectfully submitted,

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